Section 1: Identification

Product identifier:
Ceramir® Crown & Bridge QuikCap

Recommended use of the chemical and restrictions on use:
Dental cement intended for permanent cementation of restorations.
Uses advised against: Applications other than the intended use.

Details of the supplier of the safety data sheet:
Manufacturer: Doxa Dental
US and Canada contact: Doxa Dental Inc.
Axel Johanssons gata 4-6 Tel.: +46 (0) 18 478 20 00 1(855)Doxa – USA (369-2872)
SE-754 50 Uppsala www.ceramirUS.com
SWEDEN

Responsible for SDS (e-mail): info@doxa.se

Emergency phone number:
For information Canada (CANUTEC) call: 613-996-6666
Poison Emergency call 1-800-222-1222 (anywhere in the US)

Section 2: Hazard identification

The product is not controlled under WHMIS 2015 or GHS, but as a medical device under Medical Devices Regulation SOR/98-282. The labelling text is therefore shown below for safety purposes.

Physical hazards
Not applicable

Health hazards
Not applicable

Environmental hazards
Not applicable

Label elements:
Signal word
None

Symbol(s)
None

Hazard statement(s)
None

Precautionary statement(s)
None

Other hazards not otherwise classified:
Do not use in patients who have an allergy to polyacrylic acid. In very rare cases, the product may cause hypersensitivity symptoms in some patients. Discontinue use of the product if such symptoms occur and consult a doctor.

Section 3: Composition/Information on ingredients

Mixtures: The product consist of a powder base and a liquid base enclosed in a capsule (content 0.5 g).

Hazardous Components according to GHS:

<table>
<thead>
<tr>
<th>% w/w</th>
<th>Substance name</th>
<th>CAS No.</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-&lt;10</td>
<td>Polyacrylic acid</td>
<td>9003-01-4</td>
<td>-</td>
</tr>
<tr>
<td>&lt;5</td>
<td>Strontium fluoride</td>
<td>7783-48-4</td>
<td>-</td>
</tr>
<tr>
<td>&lt;5</td>
<td>Tartaric acid</td>
<td>87-69-4</td>
<td>-</td>
</tr>
</tbody>
</table>
Section 4: First-aid measures

First aid measures by route of exposure:

Inhalation:  Remove to fresh air. Get medical attention if any discomfort continues.

Skin contact: Wash skin thoroughly with soap and water. If irritation occur: Seek medical advice.

Eye contact:  Flush with water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. Do not induce vomiting. Keep at rest. Get medical attention if any discomfort continues.

Most important symptoms and effects (acute or delayed):

Inhalation of dust may irritate throat and respiratory system and cause coughing. May cause slight irritation of skin and eyes. May cause hypersensitivity symptoms in some patients.

Immediate medical attention and special treatment needed, if necessary:

Show this safety data sheet to a physician or emergency ward. Treat symptomatically.

Section 5: Fire-fighting measures

Suitable extinguishing media / Unsuitable extinguishing media:

Dry-powder, water mist (never water jet), alcohol resistant foam or carbon dioxide (CO₂).

Specific hazards arising from the chemical:

Not combustible. In case of surrounding fire the product may form hazardous decomposition products such as hydrofluoric acid.

Special protective equipment and precautions for fire-fighters:

When extinguishing fires use breathing apparatus with an independent source of air.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment - see section 8. Avoid generation and spreading of dust. Do not empty into drains. Inform appropriate authorities in accordance with local regulations.

Methods and materials for containment and cleaning up:

Sweep up and place in a suitable container. Flush area of spill with plenty of water. Further handling of spillage - see section 13. Inform appropriate authorities in accordance with local regulations in case of leakage into sewers etc. and dispose of contents/container in accordance with applicable national regulations.

Section 7: Handling and storage

Precautions for safe handling:

Use only as described in “Instruction for use”. Provide adequate ventilation. Avoid contact with skin and eyes. Wash with water and soap after work. Do not eat, drink or smoke during use.

Conditions for safe storage (including incompatible materials):

Store dry at temperatures between +4 and +25°C. Keep away from substances mentioned in section 10.

Section 8: Exposure controls/Personal protection

Control parameters, including occupational exposure guidelines

Occupational exposure limits:

<table>
<thead>
<tr>
<th></th>
<th>ACGIH TLV</th>
<th>Cal/OSHA PEL</th>
<th>NIOSH REL</th>
<th>Alberta OHS Code 2009 (8h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strontium fluoride (as F) (listed under Fluorides)</td>
<td>2.5 mg/m³</td>
<td>2.5 mg/m³</td>
<td>2.5 mg/m³</td>
<td>2.5 mg/m³</td>
</tr>
</tbody>
</table>

American Conference of Governmental Industrial Hygienists = ACGIH
National Institute for Occupational Safety and Health = NIOSH

Other exposure limit used or recommended: None known.

Appropriate engineering controls:

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Provide adequate ventilation in working areas to keep airborne concentrations low.
Section 8: Exposure Controls/Personal Protection (continued)

Individual protection measures (e.g. personal protective equipment):
PPE must follow OSHA regulations found in 29 CFR 1910.132 and should be chosen in collaboration with the supplier of such equipment. The recommended PPE and the specified standards are only suggestions, as a risk assessment of the relevant current work/operation may lease to other control measures.

Eye/face protection
Wear tight fitting safety goggles (as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or EN166).

Skin/hand protection
By prolonged contact: Wear protective gloves of for instance nitrile rubber. Breakthrough time of the ingredients is not available. Discard gloves at any suspicion of contamination.

Respiratory protection
Respiratory equipment is normally not required. In case of dust formation: Use a NIOSH/MSHA or EN149 approved respirator with a particle filter type P2. The filter has a limited lifetime and must be changed. Read the instruction.

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149.

Section 9: Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance (physical state, color, etc.)</td>
<td>Capsules</td>
</tr>
<tr>
<td>Odour</td>
<td>No characteristic odour</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined</td>
</tr>
<tr>
<td>pH</td>
<td>Not determined</td>
</tr>
<tr>
<td>Melting point/Freezing point (°C)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Initial boiling point/boiling range (°C)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Flash point (°C)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined</td>
</tr>
<tr>
<td>Flammability (solid; gas)</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Upper/lower flammable/explosive limits (vol-%)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Solubility</td>
<td>Insoluble in water</td>
</tr>
<tr>
<td>Partition coefficient - n-octanol/water</td>
<td>Not determined</td>
</tr>
<tr>
<td>Auto-ignition temperature (°C)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Decomposition temperature (°C)</td>
<td>Not determined</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not relevant</td>
</tr>
</tbody>
</table>

Section 10: Stability and reactivity

Reactivity:
Capsule content reacts with water.

Chemical stability:
Stable under normal conditions and recommended use.

Possibility of hazardous reactions:
None known.

Conditions to avoid:
Water and moisture.

Incompatible materials:
Strong oxidizers, strong acids and strong bases.

Hazardous decomposition products:
When heated to high temperatures (decomposition), the product emits very toxic fumes such as oxides of carbon and strontium and corrosive hydrogen fluoride.
Section 11: Toxicological information

Information on toxicological (health) effects:

Likely routes of exposure: Inhalation, skin and ingestion.

Symptoms:
Symptoms may occur if dust is released from the capsule by accident.

Inhalation:
Inhalation may cause irritation of the respiratory system.

Skin contact:
May cause slight irritation with redness.

Eye contact:
May cause slight irritation with redness and stinging.

Ingestion:
May cause irritation of the gastrointestinal tract, nausea, vomiting, salivation, fever and headache.

Delayed and immediate effects and chronic effects from short-term and long-term exposure:
High concentration of inorganic fluorides may cause skeletal fluorosis with symptoms such as periodical pain and stiffness in the joints, headache, abdominal pain and muscle weakness. Later osteoporosis and bone damages may occur. Loss of weight. Anorexia and anaemia are common findings in fluorine poisoning. Skin sensitization to polyacrylic acid may occur in very rare cases. Symptoms are redness, itching and eczema.

Acute toxicity

<table>
<thead>
<tr>
<th>Hazard class</th>
<th>Data</th>
<th>Test</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td>No available data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>LD$_{50}$ (rat) &gt; 2000 mg/kg (Tartaric acid)</td>
<td>OECD 402</td>
<td>RTECS</td>
</tr>
<tr>
<td>Oral</td>
<td>LD$_{50}$ (rat) = 2500 mg/kg (Polyacrylic acid)</td>
<td>No data</td>
<td>Supplier</td>
</tr>
<tr>
<td></td>
<td>LD$_{50}$ (rat) &gt; 10600 mg/kg (Strontium fluoride)</td>
<td>No data</td>
<td>RTECS</td>
</tr>
<tr>
<td></td>
<td>LD$_{50}$ (rat) &gt; 2000 mg/kg (Tartaric acid)</td>
<td>OECD 423</td>
<td>RTECS</td>
</tr>
<tr>
<td>Corrosion/irritation:</td>
<td>Irritant to skin and eyes (Polyacrylic acid)</td>
<td>No data</td>
<td>Supplier</td>
</tr>
<tr>
<td></td>
<td>In vitro eye irritant (Tartaric acid)</td>
<td>OECD 437</td>
<td>ECHA diss.</td>
</tr>
<tr>
<td></td>
<td>No skin irritation, rabbit (Tartaric acid)</td>
<td>OECD 404</td>
<td>RTECS</td>
</tr>
<tr>
<td>Sensitization:</td>
<td>Not a skin sensitizer (Tartaric acid)</td>
<td>OECD 429</td>
<td>RTECS</td>
</tr>
</tbody>
</table>

The chemical, physical and toxicology properties of strontium fluoride have not been thoroughly investigated and recorded.

Mutagenic toxicity
No available data/insufficient data.

Reproductive toxicity
No available data/insufficient data.

Carcinogenic toxicity
No available data/insufficient data.
Substances are not mentioned on NTP’s Report on Carcinogens (RoC), latest ed.
Substances are not found to be potential carcinogens in IARC Monographs, or by OSHA.

Specific Target Organ Toxicity – single exposure / repeated exposure
No known effects.

Aspiration toxicity
No known effects.
Section 12: Ecological information

Ecotoxicity:

<table>
<thead>
<tr>
<th>Aquatic</th>
<th>Data</th>
<th>Test (Media)</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish</td>
<td>LC₅₀ (Brachydanio rerio, 96h) &gt; 100 mg/l (Polyacrylic acid)</td>
<td>No data (FW)</td>
<td>Supplier</td>
</tr>
<tr>
<td>Crustaceans</td>
<td>EC₅₀ (Daphnia magna, 48h) &gt; 100 mg/l (Polyacrylic acid)</td>
<td>No data (FW)</td>
<td>Supplier</td>
</tr>
<tr>
<td></td>
<td>EC₅₀ (Daphnia magna, 48h) = 93.3 mg/l (Tartaric acid)</td>
<td>OECD 202 (FW)</td>
<td>Supplier</td>
</tr>
<tr>
<td>Algae</td>
<td>EC₅₀ (Scenedesmus subspicatus, 72h) &gt; 180 mg/l (Polyacrylic acid)</td>
<td>No data (FW)</td>
<td>Supplier</td>
</tr>
<tr>
<td></td>
<td>EC₅₀ (Algae, 72h) = 51.4 mg/l (Tartaric acid)</td>
<td>OECD 201 (FW)</td>
<td>Supplier</td>
</tr>
</tbody>
</table>

Persistence and degradability
Methods for determination of degradability are not valid for inorganic compounds.
Polyacrylic acid is not considered readily biodegradable.
Tartaric acid was degraded 85% in 28 days at an OECD 306 test and is considered rapidly degradable.
The cured product is not expected to be biodegradable.

Bioaccumulative potential
Polyacrylic acid: Log K_{ow} = 0.44 (no significant bioaccumulative effect).
Tartaric acid: Log K_{ow} = 0.24 (no significant bioaccumulative effect).

Mobility in soil
Low mobility in soil is expected.

Other adverse effects
None known.

Section 13: Disposal considerations

Safe handling for disposal and methods of disposal, including any contaminated packaging
This material and its container must be disposed of as non-hazardous waste.

Inform appropriate authorities in accordance with local regulations in case of leakage into sewers etc. and dispose of contents/container in accordance with applicable national regulations.

Dispose/incinerate of contents/container and waste product in accordance with applicable local/regional/national/international regulations in a permitted waste incineration facility/industrial waste facility or at licensed waste disposal sites.

Section 14: Transport information

Not dangerous goods according to Canadian Transportation of Dangerous Goods (TDG)/IMDG/IATA.
UN-no.: None.
UN proper shipping name: None.
Transport hazard class(es): None.
Packing group: None.
Environmental hazards: None.
Transport in bulk, if applicable: Not applicable.
Special precautions: None.

Section 15: Regulatory information

Safety, health and environmental regulations specific to the product:
Inventories
Status on Non-Domestic Substances List/Domestic-Substance List (N-DSL/DSL) (Canada):
All ingredients of this product are DSL Listed.

This SDS has been prepared to meet requirements according to Canadian WHMIS 2015.
Section 16: Other information

Abbreviations:
ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
WEEL = Workplace Environmental Exposure Level
EC$_{50}$ = Effect Concentration 50%
FW = Fresh Water
IATA = International Air Transport Association
IMDG = International Maritime Dangerous Goods
LC$_{50}$ = Lethal Concentration 50%
LD$_{50}$ = Lethal Dose 50%
NIOSH = National Institute for Occupational Safety and Health
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
STEL = Short-term exposure limits
TWA = Time Weighted Average
WHMIS = Workplace Hazardous Materials Information System

Literature:
ECHAdiss. = REACH Registration dossier from ECHA’s home page.
IARC = International Agency for Research on Cancer
RTECS = Register of Toxic Effects of Chemical Substances

Other information:
No special training is required. However, the user should be well instructed in the execution of his/her task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.
The above information, which is accurate to the best of our knowledge and belief, describes the safety aspects of our product but does not warrant any product properties.

Changes since the previous edition:
Not relevant.

Prepared by: Altox a/s – Tonsbakken 16-18 – DK-2740 Skovlunde - Phone +45 - 38 34 77 98 / PH - Quality control: PW